CONTINUOUS QUALITY IMPROVEMENT IN THE HUMAN RESEARCH PROTECTION PROGRAM

1. **PURPOSE:** To establish a Continuous Quality Improvement (CQI) program to evaluate Human Research Protection Program effectiveness and conduct quality improvement activities to continuously measure, assess and improve compliance with institutional HRPP policies and practices to protect human research participants. The CQI program is to help ensure that research projects involving human research participants are adhering to the Institutional Review Board (IRB) and Research & Development Committee (R&D) approved protocol, conducting the informed consent process appropriately and in both the investigator and R&D Service research files are properly maintained.

2. **POLICY:** Research projects involving human research participants active at the Portland VA Medical Center (PVAMC) must be conducted in accordance with institutional HRPP policies and procedures as well as state and federal regulations. Any research project which is active at the PVAMC and involves human research participants may be subject to an audit composed of the review and evaluation of adherence to HRPP requirements, investigator and R&D Service research files, informed consent documents, and pharmacy log books. The R&D Service will randomly evaluate compliance with HRPP and IRB requirements on an annual basis.

3. **RESPONSIBILITIES:**

   a. The **Associate Chief of Staff for Research & Development** is responsible for developing and managing policies and procedures for evaluating HRPP effectiveness at the PVAMC, as well as assess and improve compliance with HRPP policies and practices to protect human research participants.

   b. The **Research and Development Committee (R&D)** is responsible for:
      (1) Reviewing and evaluating performance evaluations regarding HRPP CQI audits. This includes investigator compliance with HRPP and IRB requirements.
      (2) Making any recommendations, as needed, regarding appropriate corrective actions, proposed regarding the reports and results of compliance assessment and quality improvement activities (QA/QI) related to research.
      (3) Voting on any recommendations for action proposed by the IRB on all CQI reports.

   c. The **Institutional Review Board (IRB)** is responsible for:
      (1) Participating in the HRPP CQI audits, when additional expertise or assistance is needed.
      (2) Reviewing performance evaluations brought forth to the IRB, regarding CQI audits.
      (3) Making recommendations regarding proposed quality improvement efforts and/or measures to improve performance, regarding reports brought forth to the IRB.
      (4) Voting on all recommendations for action to be forwarded to the R&D Committee.

   d. **Research Assurance and Compliance Coordinator (RACC)** is responsible for:
      (1) Coordinating a mutually convenient audit appointment and place with the Principal Investigator (PI) and/or his or her designee and the Research Pharmacy, when applicable.
      (2) Preparing the audit documents.
      (3) Reviewing the research project file located in the R&D Service prior to the scheduled audit.

(4) Conducting the audit of the research project.
(5) Communicating the audit results to the PI and/or his/her designee.
(6) Forwarding audit reports to the IRB and ACOS/R&D for review and evaluation as completed and to the R&D Committee quarterly.

e. **Principal Investigators** (PI) are responsible for:
(1) Coordinating the research project audit date and place with the RACC.
(2) Ensuring that all study related documents are available for review.
(3) Assembling and preparing study related documents.
(4) Cooperating with audit procedures.
(5) Complying with decisions made by the RACC, IRB and/or R&D Committee regarding audit findings and recommendations.

4. **PROCEDURES:**

a. **CQI Audits**
(1) The RACC and/or the IRB Chair, members and/or staff will conduct the CQI audits.
(2) The individuals conducting the HRPP CQI audit will be knowledgeable of and familiar with the protocol to be reviewed, audit procedures, clinical trials methodology, PVAMC policies and state and federal regulations, regarding research involving human research participants.
(3) The individual(s) conducting the audit may not be associated with the conduct of any procedure(s) in the research project to be reviewed.

b. **Identification of Research Projects to be Audited**
(1) Any PVAMC IRB approved research project, in which human research participants are currently enrolled, may be audited.
(2) Research projects to be audited will be identified through a randomization process with research projects designated as high risk being first priority.
(3) At least 12 research projects will be audited per year.
(4) A for cause audit may be requested by the RACC, IRB, R&D Committee or ACOS/R&D at any time if deficiencies or peculiarities are identified during the review process or otherwise.

c. **Coordinating the Audit**
(1) The RACC will notify the PI, regarding the audit.
(2) If the research project involves an investigational drug, the RACC will also contact the Research Pharmacy, regarding the audit of the related Research Pharmacy drug logs.
(3) The date, time and place of the audit(s) will be coordinated between the RACC and PI and/or designee, and when applicable the Research Pharmacy. The audit will occur approximately 30 days from the date of contact, depending on the PI's and Research Pharmacy's circumstances.

d. **Audit Preparations**

(1) Prior to the audit, the individual(s) conducting the audit will review the IRB and R&D Committee minutes regarding the research project and the research project file maintained by the Research Service, including the:
   (a) Proposed Project Questionnaire;
   (b) Protocol;
   (c) Initial Review Questionnaire and applicable attachments;
   (d) Informed Consent Form(s), if applicable;
   (e) IRB Correspondence and Approvals;
   (f) R&D Committee Correspondence and Approvals;
   (g) Amendment(s), if applicable;
   (h) Advertisement(s), if applicable;
   (i) Continuing Review Material(s), if applicable;
   (j) Other regulatory and/or study coordinating center documents and adverse events.

(2) The RACC will complete the R&D Service Research Project File Audit Checklist (Appendix A) for each research project prior to the audit.

(3) If individuals in addition to the RACC will be participating in the audit, the individuals will meet to discuss the audit procedures and any deficiencies.

e. **Scope of Review**

(1) Research Participant Files
   (a) A sampling of the research participants files for research participants recruited in the study will be reviewed. The selection of the files to be reviewed will be random, however, any patient case may be selected for review.
   (b) Source documents may include, but are not limited to, the following:
      i. Progress notes documenting: the informed consent form process; when the subject is actually entered in the study; and when the subject's participation is terminated;
      ii. Informed Consent Forms; and
      iii. Subject scheduling records, if applicable.

(2) Investigator research files including those items in Section f. (3).

(3) The Investigator Research Project File Audit Checklist (Appendix B) will be completed for each audit.

f. **Audit Overview**

(1) The topics measured may include:
   (a) adhering to HRPP policies;
   (b) using only IRB approved advertisements and subject recruitment materials;
   (c) obtaining consent prior to initiating any research related procedures;
   (d) consent obtained only by trained and authorized individuals;
   (e) using only the IRB approved consent form;
   (f) ensuring that the informed consent form is appropriately signed and dated;
   (g) verifying documentation of the informed consent in the progress notes;
   (h) verifying documentation that a copy of the signed informed consent form has been provided to the subject or legally authorized representative;
   (i) reconciling adverse events between the PI and IRB records;
   (j) adhering to IRB approved protocols and conditions; and

(k) adhering to policies regarding storage, security and dispensing of investigational devices.

(2) The research project audit is composed of the review and evaluation of the following:
   (a) research project file maintained by the R&D Service;
   (b) nvestigator research files; and
   (c) Research Pharmacy Log Books, when applicable.

(3) Adherence to institution HRPP policies and procedures, state and federal regulations will be evaluated. These will include:
   (a) initial IRB Approval of the protocol, consent form, and any other documents, e.g. advertisement, subject recruitment material, grant application, etc. reviewed during the initial review by the IRB.
   (b) initial R&D Committee approval of the research project.
   (c) required IRB Notifications (i.e. unanticipated problems, adverse events, deviations from the protocol, etc.).
   (d) continuing Review IRB approval(s), appropriate to the schedule for continuing review.
   (e) annual R&D Committee continuing review approvals.
   (f) IRB approval(s), for any modifications to the research project during the period from initial review to continuing review, e.g. protocol amendments, consent form revisions, etc.

(4) The PI and/or his/her designee is encouraged to be present during the audit process to answer any questions or clarify any uncertainties.

(5) The results of the audit will be communicated to the PI and/or research staff in a face-to-face meeting.

(6) The written report regarding the audit results and recommendations for any improvements to better comply with the HRPP, will be sent to the Principal investigator within two weeks of the audit.

(7) The PI must submit a response and any corrective action needed to the RACC within 30 days of receipt of the written report.

(8) The audit results will be forwarded and evaluated by the IRB and ACOS/R&D.

(9) When applicable, the IRB will review performance evaluations brought to the committee, regarding continuous quality improvement audits and will vote on any recommendations for action to be forwarded to the R&D Committee.

(10) The audit results and any corrective action needed will be submitted to the R&D Committee with the IRB meeting minutes.

(11) The R&D Committee will review the performance evaluations brought to the committee and make and vote on any recommendations for action regarding proposed quality improvement efforts and/or measures to improve performance.

(12) Trends in audit report data will be identified and topics for annual or immediate education will be selected as needed.

5. REFERENCES: Oregon Health & Science University Cancer Institute Data & Safety Monitoring Plan

6. CONCURRENCES: Endorsed by the Research & Development Committee 12/15/2003

7. RESCISSION: None

8. FOLLOW-UP RESPONSIBILITY: ACOS, Research & Development Service (R&D)

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